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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,816	09/25/2003	Vernon G. Wong	440882000201	6866

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EXAMINER	
KENNEDY, SHARON E	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,816	WONG ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/05/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,37-39,42-47,51,52,55,56,61-67 and 82-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,37-39,42-47,51,52,55,56,61-67 and 82-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Claim Rejections - 35 USC § 103

Claims 35, 37-39, 42-47, 51, 52, 55, 56, 61-67, 82-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong '079. See the comments set forth in the previous office action.

Response to Arguments

Applicant's arguments filed October 5, 2006 have been fully considered but they are not persuasive. Essentially, applicant argues that the claims are patentable since they do not recite a release modifier. Note is made of applicant's claim version of November 21, 2005, which included the language "without an added release modifier." The examiner subsequently rejected this language as containing new matter in the office action dated January 12, 2006. Thereafter, applicant changed the claims to delete this phrase. In the claim version of October 5, 2006, applicant has changed the transitional phrase from "comprising" to --consisting essentially of--". Applicant states that this change is supported by paragraph [0056] of the filed specification (which corresponds to [0065] of the published version) and eliminates the possibility of the claim including the ingredient of the release modifier. However, this is not convincing.

Whether or not changing the transition phrase of the claim from "comprising" to -- consisting essentially of-- eliminates the possibility of applicants device containing a release modifier is of issue here. MPEP 2111.03, entitled *Transitional Phrases*, offers guidance in what defines the scope of a claim having different transitional phrases. The relevant portion is reproduced below for applicant's convenience.

> The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.").

Applicant states that the release modifier is now eliminated, but the examiner disagrees. As required by the MPEP, determining what ingredients are eliminated by the phrase "consisting essentially of" is ascertained by examining the specification. Does the modifier change the material aspects of the claimed invention? Does the specification provide a "clear indication" as required by *PPG* in this regard? Reading the specification with a fresh eye, with particular care taken to finding evidence that eliminating the release modifier materially changes the aspects of the invention, offers little support for applicant's position.

The first mention of release modulators occurs deep into applicant's description of the invention, even after the "shopping lists" of antibacterials, antineoplastics, antifungals, antibiotics, etc., See paragraph [0060] of applicant's published specification, US 2004/0057979. Further, that paragraph states that release modulators may be included. The paragraph states, "Additionally, release modulators such as those described in U.S. Pat. No. 5,869,079 may be included in the implants (emphasis added). The amount of release modulator employed will be dependent on the desired release profile, the activity of the modulator, and on the release profile of the glucocorticoid in the absence of modulator." Applicant's published paragraph [0062] also discusses the use of release modifiers, and states that the inclusion of these components are dependent upon the "proportions" of the implants. Note is made of applicant's published paragraph [0064], which happens to eliminate the modifier, however, these experimentals are also provided in the prior art patent, and no guidance

is provided that makes the elimination of the release modifier novel, other than what is provided by applicant's arguments only after the prior art rejection in view of Wong.

Since the specification provides no guidance in what is meant by "consisting essentially of" with respect to the release modulator, the examiner takes the position that the transitional phrase "consisting essentially of" does not eliminate the possibility of the release modifier.

Assuming for the sake of argument that the claim does eliminate the release modulator as amended, Applicant's arguments would still fail to be persuasive. Applicant argues that the weight of the device, the agent release percentages after certain time periods, the weight percent of the device, etc., are significant and patentable difference in view of the prior art. However, these are routine considerations in designing various "prescription type" implants for various patients. These are merely determinations made by ocular care physicians during the course of an ordinary working day. Further, these arguments are of little value in view that the release rate of the implant is highly dependent upon the placement of the device (applicant's published paragraph [0077]), so little probative value can be placed on applicant's arguments that the elimination of a release modifier yields an implant with a surprisingly different release profile (applicant's arguments filed October 5, 2006, pages 8-10). Accordingly, the claims must be rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon E. Kennedy
Primary Examiner
Art Unit 1615